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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,388

08/19/2003

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,388	<b>Applicant(s)</b> VANTASSEL ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 8-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the amendment filed 7/28/2008 in which claim 1 was amended and claims 17-27 were added (but have already been presented as "new"). Currently claims 1-27 are pending for examination, with claims 3-7 and 22-27 are withdrawn from a previous office action and the current action.

### ***Election/Restrictions***

The submitted claims 22-27 (see office action dated 1/23/2008) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method claims are patentably distinct because they are drawn to a specific treatment area and the steps of implantation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 8-10, 13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 2 and 16, the amendments add different elements described as various “hubs”, Applicant’s disclosure does not reference any hub sections with respect to any of the drawings.

Regarding claim 1, the first mentioned membrane “permanent membrane” is also later referenced as a “filtering membrane”, thus lacking antecedent basis. Additionally another “associated membrane” is referenced; it is unclear whether this membrane is the previously referenced “permanent membrane” or another new membrane element.

Regarding claims 8-10, the claims reference “fingers”, which lack antecedent basis in independent claim 1.

Regarding claim 13, the claim references a “support structure” which “is a membrane support”, however in the independent claim 1, the “support structure” further comprises “a membrane support frame”, it is unclear whether the support structure is the membrane support or if the membrane support is a separate structure. Additionally, the “filtering membrane” is again referenced.

For the purposes of examination of this application, the Examiner will assume that there is only one membrane element and the support element in a singular element with the membrane support.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 10-13, and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottenceau et al. (USPN5,375,612). Cottenceau et al. discloses a blood filter.

Regarding claims 1, 2, 8, 10-13 and 15-21, Cottenceau et al. discloses apparatus (Figures 1, 3) capable of permanent placement across an ostium of a left atrial appendage in a patient, comprising: a permanent membrane (9) configured to extend across the ostium of the left atrial appendage, and a support structure (7) having a first deployed shape configuration (Figure 15) having a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, and having a second retracted shape configuration (Figure 14) having a radially reduced medial portion to fit within a delivery catheter in an undeployed state (Figure 13); said support structure (7) having a first distal hub area (end near 17a) where radially deployable limbs (7) are gathered together in both the deployed and retracted state, a second medial hub (near 11) area where deployable limbs are gathered together in both the deployed and undeployed state, and a third proximal hub area (near 15) facing the left ventricle when in the deployed state, said support structure being the membrane support frame (near 17b) and the associated membrane (9) wherein the filtering membrane is attached to the support structure and capable of extending across the ostium of the left atrial appendage when the deployable medial portion engages the interior of the left atrial appendage wherein the support structure (7) comprises a plurality of finger (19) with each having a first end portion (tip of 19), a second end portion (near 21), and a medial portion (between 21 and 19), and wherein the medial portion of each finger (19) is

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radially outwardly expanded in the second configuration with the finger member being fabricated of stainless (col 4, ln 30-40). Cottenceau et al. discloses a delivery actuation device (43, 45) configured to remotely radially expand the support structure (See Figures 1, 3 and 13-15).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8, 10-13, 15-19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesh et al. (USPN6,152,144). Lesh et al. discloses a method and device for left atrial appendage occlusion.

Regarding claims 1, 2, 8, 10-13, 15-19 and 21, Lesh et al. discloses apparatus (Figures 3a, 3b) capable of permanent placement across an ostium of a left atrial appendage in a patient, comprising: a permanent membrane (63) configured to extend across the ostium of the left atrial appendage, and a support structure (11) having a first deployed shape configuration (Figures 10-12) having a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, and having a second retracted shape configuration (Figures 10-12) having a radially reduced medial portion to fit within a delivery catheter in an undeployed state; said support structure

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(11) having a first distal hub area where radially deployable limbs (29, 11) are gathered together in both the deployed and retracted state, a second medial hub area where deployable limbs are gathered together in both the deployed and undeployed state, and a third proximal hub area facing the left ventricle when in the deployed state, said support structure being the membrane support frame and the associated membrane (63) wherein the filtering membrane is attached to the support structure and capable of extending across the ostium of the left atrial appendage when the deployable medial portion engages the interior of the left atrial appendage wherein the support structure (29) comprises a plurality of finger (29a) with each having a first end portion, a second end portion, and a medial portion, and wherein the medial portion of each finger (29a) is radially outwardly expanded in the second configuration with the finger member being fabricated of stainless (col 2, ln 20-50). Cottenceau et al. discloses a delivery actuation device (Figure 9) configured to remotely radially expand the support structure (See Figures 1-23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 14 are rejected under 35 U.S.C 103(a) as being unpatentable over Cottenceau et al. (USPN5,375,612) or Lesh et al. (USPN6,152,144).

Regarding claims 9 and 14, Cottenceau et al. (or Lesh et al.) discloses the claimed invention except for the support structure being composed of nitinol or a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the materials as claimed by Applicant in order to achieve proper expansion and delivery inside the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

### ***Response to Arguments***

Applicant's arguments filed 07/28/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the prior art references do not disclose the different hub section elements (distal, medial and proximal).

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the prior art reference meets the claim limitations as disclosed and claimed. The prior art references each have a support structure (see



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above) the term "hub" denotes no special meaning or structure. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997). See MPEP §2111 - §2116.01 for case law pertinent to claim analysis. Therefore without any expressly disclosed definition by the Applicant, the Examiner considers the "hub" elements to be different portions of the support structure.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/15/2008

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763